IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Kevin A. Kelly Thomas E. Lach Ralph D. Lach Arthur W. Handshy	Group Art Unit 3764
		Examiner: T. M. Nguyen
Serial No:	10/633,938	
Filed:	August 4, 2003	
For:	CHEST COMPRESSION APPARATUS FOR CARDIAC ARREST	

DECLARATION OF THOMAS E. LACH

The Commissioner for Patents
P.O. Box #1450
Alexandria, Virginia 22313-1450

Sir:

Thomas E. Lach declares that:

TEL 6-16-11

1. He is the owner and president of Deca-Medics, Inc., a company that he established prior to the date of September 28, 1994. This company was established for the purpose of developing and marketing CPR equipment that incorporated the invention(s) of the patent application identified above and the applications from which it claims priority.

2. The attached Exhibits A to E were all created prior to September 28, 1994. They all have dates on them, which dates are prior to September 28, 1994. These dates have been deleted for the purposes of this declaration as indicated on the exhibits themselves.

3. The first date on which anyone at Deca-Medics, Inc., or any of the inventors of the invention of the application identified above had any knowledge of any development

by Roman Szpur in the field of CPR was on September 28, 1994. On that date, Mr. Szpur showed them the drawing, a copy of which is attached as Exhibit F.

4. The attached Exhibit A shows a manually operated CPR device invented and developed by the inventors of the subject patent application identified above.

5. The attached Exhibit B gives the specifications for a CPR apparatus that will operate mechanically. This means that the force required for the CPR is provided by a motor rather than a human being. It also operates automatically. Exhibit C gives a drawing of a mechanical device for providing mechanized, automated CPR. It corresponds to Figure 9 of the subject application.

6. The attached Exhibit D give a diagram of a mechanized CPR device drawn by one of the inventors of the application identified above. It also gives calculations for the forced required to accomplish mechanized CPR.

7. The attached Exhibit E gives specifications for manufacturing a mechanically driven CPR device. It was written by a contractor retained by Deca-Medics, Inc., and was based on information supplied to the contractor by the inventors of the application identified above. It also requests information from Deca-Medics, Inc., in order to allow the project to proceed.

8. The attached Exhibit G shows a device actually built by Deca-Medics., Inc., under my direction. It incorporates the principles set forth in the application identified above. It corresponds to the attached Exhibits C and D as well as Figure 9 of the patent application. This device was built prior to September 28, 1994. The work on this device was performed expeditiously after the completion of the drawings of the attached Exhibits C and D.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application identified above or any patent issued thereon.

Thomas E. Lach

June 16, 2011

Deca-Medics, Inc.
777 W. State Street, Suite 204
Columbus, OH 43222
(614) 221-5600 Fax (614) 221-2081

New Product Specifications

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The is an inthoracic CPR device based on the concept of a band that circumvents the thorax of a person suffering Cardiac Arrest.

1. The device on the center of the victims chest and wrapping the band around the chest and securing it to both sides of the device.

2. Once the band is secured, the person attempting to resuscitate the other individual pushes down on the device on the center of the chest causing the device to tighten the band and thus increasing the inthoracic pressure. This transfer of energy may be accomplished through the use of a screw gear and take reels, the use of pivoting Cam arms that increases the mechanical advantage of the force, or other methods for forcing the take up of the band to actuate thoracic compression.

3. Built into the device will be a mechanism for the release of kinetic energy stored during compression and sudden released by the withdraw of downward force. In addition, the base of the device will incorporate a sticky pad that will attached to the chest. Therefore, the release of the pumper will actually facilitate decompression.

NOTARIZED THIS (Deleted)

Doris M. Waldron
DORIS M. WALDRON
EXP: 5/19/96

Exhibit A

DECA-MEDICS, INC.

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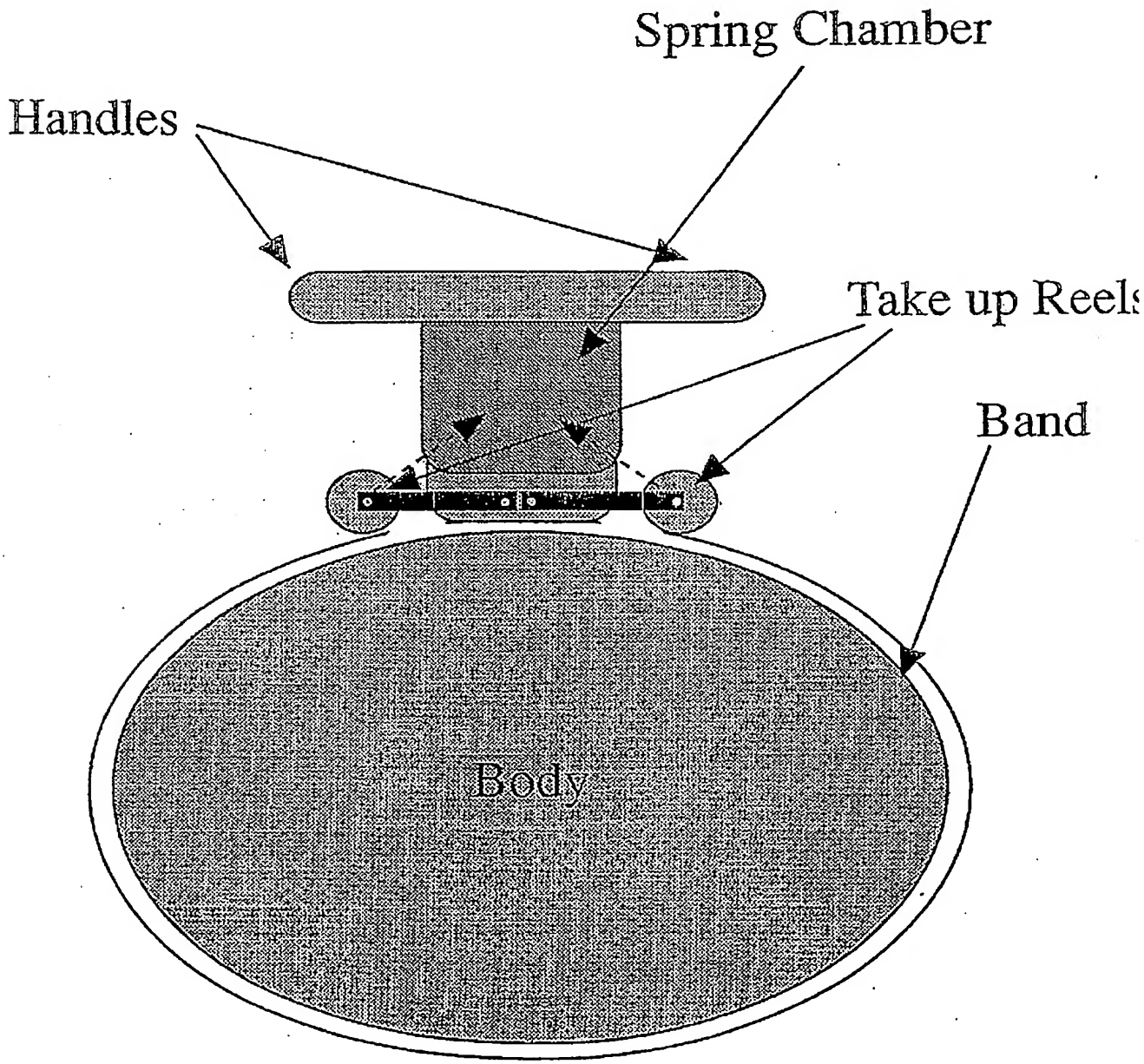
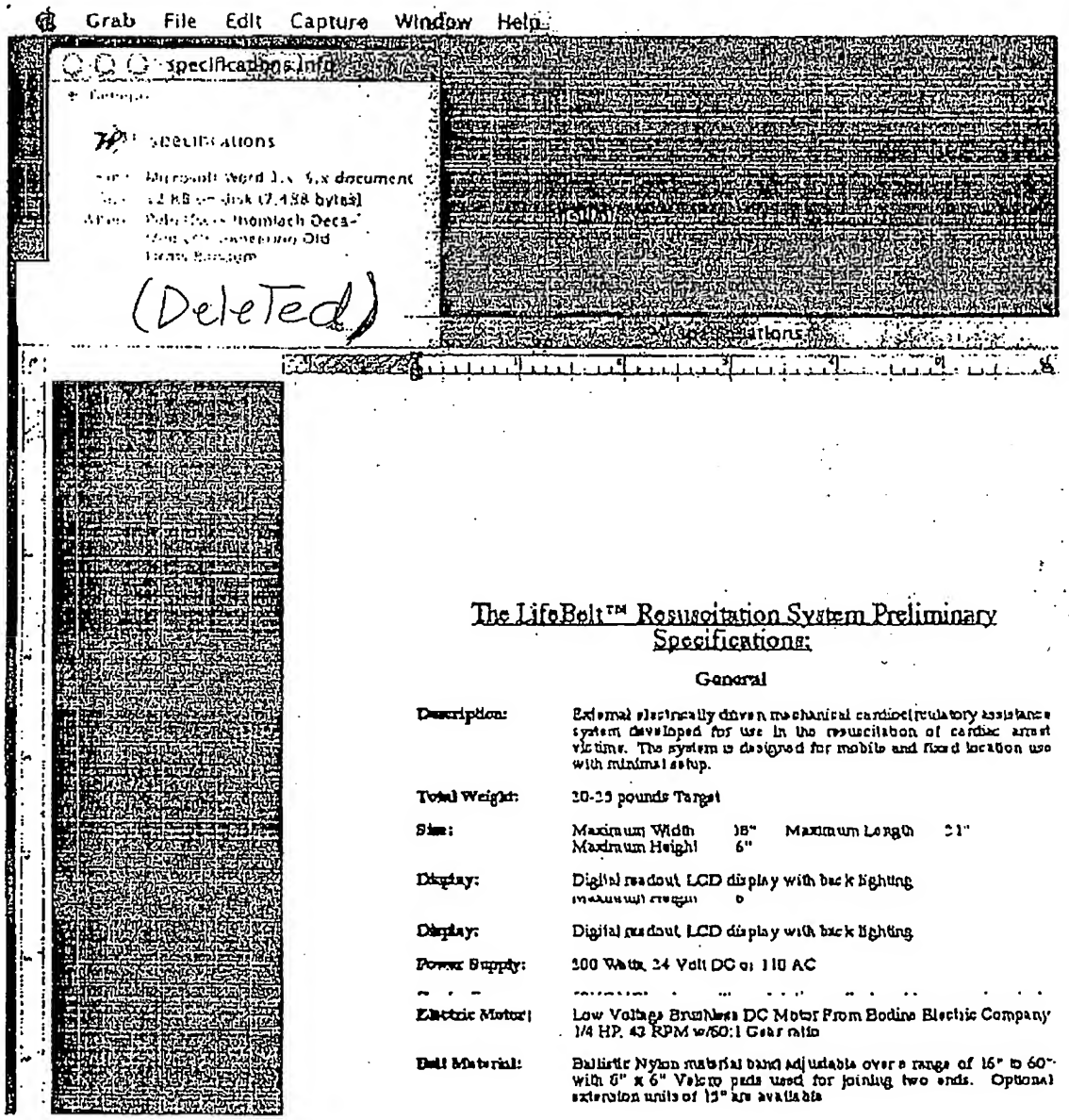


NOTARIZED THIS (Deleted)

Doris M. Waldron

DORIS M. WALDRON
EXP: 5/19/96



The LifeBelt™ Resuscitation System Preliminary Specifications:

General

Description:	External electrically driven mechanical cardiocirculatory assistance system developed for use in the resuscitation of cardiac arrest victims. The system is designed for mobile and fixed location use with minimal setup.
Total Weight:	20-25 pounds Target
Size:	Maximum Width 18" Maximum Length 21" Maximum Height 6"
Display:	Digital readout LCD display with back lighting
Display:	Digital readout LCD display with back lighting
Power Supply:	200 Watts 24 Volt DC or 110 AC
Electric Motor:	Low Voltage Brushless DC Motor From Bodine Electric Company 1/4 HP, 43 RPM w/50:1 Gear ratio
Belt Material:	Ballistic Nylon material band adjustable over a range of 16" to 60" with 6" x 6" Velcro pads used for joining two ends. Optional extension units of 15" are available

Exhibit B

The LifeBelt™ Resuscitation System Preliminary Specifications:

General

Description:	External electrically driven mechanical cardiocirculatory assistance system developed for use in the resuscitation of cardiac arrest victims. The system is designed for mobile and fixed location use with minimal setup.
Total Weight:	20-25 pounds Target
Size:	Maximum Width 18" Maximum Length 21" Maximum Height 6"
Display:	Digital readout, LCD display with back lighting
Power Supply:	200 Watts, 24 Volt DC or 110 AC
Controller:	68HC11F1 pulse width modulation with closed loop speed control
Battery Life:	Target battery life up to 20 minutes
Electric Motor:	Low Voltage Brushless DC Motor From Bodine Electric Company 1/4 HP, 42 RPM w/60:1 Gear ratio
Belt Material:	Ballistic Nylon material band adjustable over a range of 16" to 60" with 6" x 6" Velcro pads used for joining two ends. Optional extension units of 15" are available
Safety Features:	System limitations maintained in non-user accessed software. Emergency shut-off and quick release switch. Hand crank for manual drive in the event of power loss

External Thoracic Compression

Description:	A supple band surrounds the chest of an individual and is tightened and released by the motor or manual controlled movement of the take up reel. In addition, the placement of the concentrator between the sternum and the band will focus the compression force on the sternum.

Sternum Compression Force:

System defaults allow for sternum compression of 60 lbs. and is continuously adjustable up to 130 pounds

Repetition of Compression:

System compresses at a default rate of 60 cpm. is continuously adjustable up to 80 to 120 cpm.

Compression Cycle:

Compression cycle will allow for compression of the thorax for 50% of the cycle.

Highlights and Advantages

- Greater circulation due to the combination of cardiac and thoracic compression.
- Reduction in physical requirements of properly administering CPR
- Able to generate compression force and repetition of High Impulse CPR
- Reduction of personnel requirements for EMS providers for properly administering CPR
- Improved safety considerations for EMS personnel attempting to perform CPR while in transit
- Potentially, less organ damage due to greater surface area involved in CPR

Future Enhancements

Description:

Future system will be designed to reduce the amount of human involvement required to properly resuscitate a cardiac arrest victim. Therefore, once the LifeBelt system has been fastened around a victims thorax, a computer controller will initiate Electrocardiophy. Based on programmed interpretation of the signal, the system would respond to the patient condition. In a manner yet to be determined, the system will either analyze oxygenation, or the coronary perfusion gradient and will respond with CPR, defibrillation, or cardiac pacing.

The incorporation of an endotracheal tube or tracheal intubation would allow for synchronization of compression and ventilation. In addition, the system would be able to monitor PCO_2 readings to determine the effectiveness of resuscitation efforts.

Additionally, the system will combine chest compression and circumferential defibrillation to reduce the amount of electric shock required for resuscitation, thus, reducing damage to myocardial tissue.

An easy to use key pad will allow for recording of the drug, dosage and exact time of administering so that the effects may be recorded for future analysis and record keeping.

A printout of the system's response to the changing conditions of the patient will be compiled into an easy to read report that will quickly inform the doctor of prior intervention.

Targeted Weight With Enhancements: 45-50 pounds

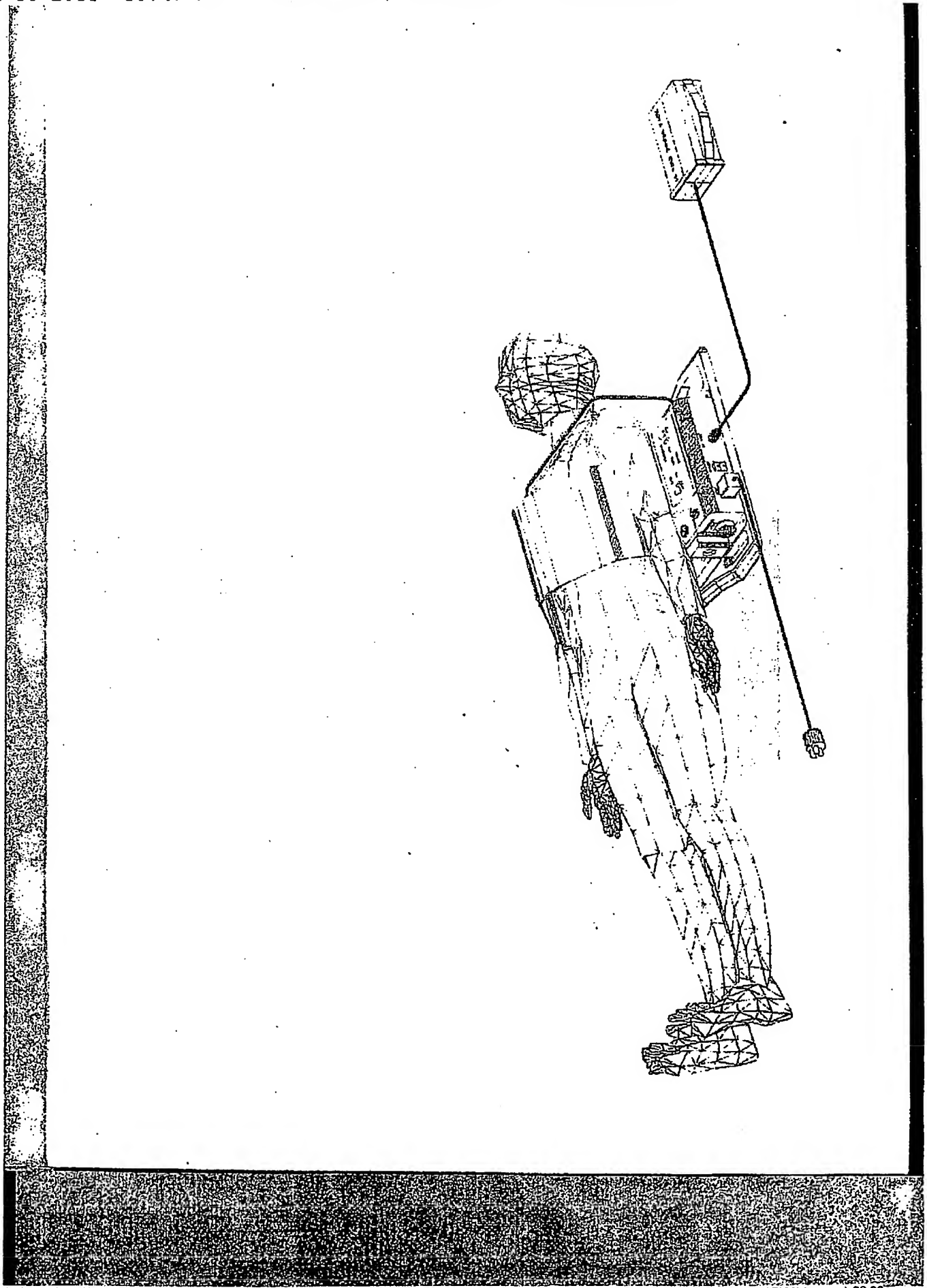
Company Overview

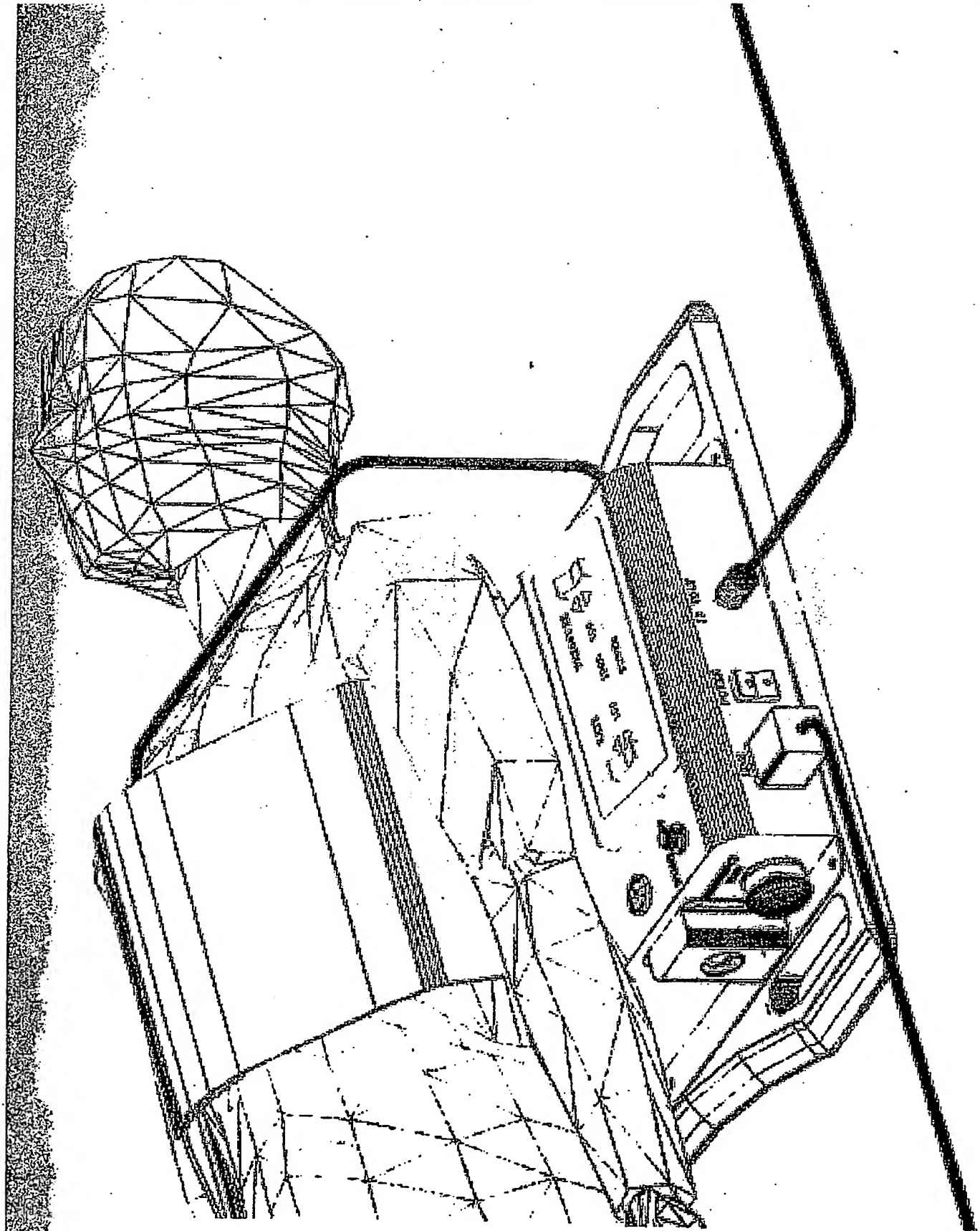
Thomas E. Lach
President and CEO

(Deleted)

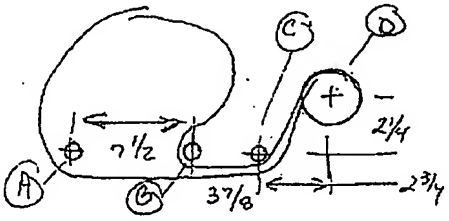
Exhibit C

777 W. State Street, Suite 204 • Columbus, Ohio 43222 • Phone (614) 221-5600 • FAX (614) 221-2081

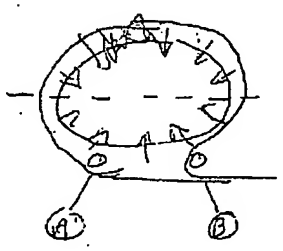




(Deleted) FORCE CALCULATIONS



Assume:
MAX Pressure = 500mm Hg (9.66psi)
Belt width = 8"
MAX Chest Diameter = 20"



Free Body Diagram of Chest

$$T = \frac{P \cdot A_{\text{Diameter}}}{2} = \frac{9.66 \times 8 \times 20}{2} = \frac{1545.6}{2} = 772 \text{ lbs}$$

The Max force will be on (B) AND can approach as a Maximum $2T = 1545$ lbs.

Exhibit D

Kevin A. Kelly
Deleted

Random®
CORPORATION
591 Northland Blvd.
Cincinnati, Ohio 45240
Tel: (513)825-0880
Fax: (513)742-2775

(FAX Cover Sheet)

To: DECA-MEDICS

Attn: THOM LACH Ext —

From: Will Atkinson

Date (Deleted)

Transmitting 5 Pages, Including This Cover Sheet

THOM

HERE IS THE SPEC SO FAR. OBVIOUSLY IT STILL NEEDS A LOT OF WORK. THIS SHOULD GIVE YOU AN IDEA OF THE FORMAT AND CONTENT THAT WE INTEND TO USE. ANY COMMENTS OR INFORMATION RELATED TO "FILLING IN THE BLANKS" WOULD BE APPRECIATED.

WEA

Exhibit E

1.0 Scope

With respect to the LifeBelt Resuscitation System, this document fulfills the requirements of Procedure, Product Design Control for a Product Specification.

2.0 Definitions

System: LifeBelt Resuscitation System

3.0 References

A139-18956 Procedure, Product Design Control
A139-18846 Policy, Quality Manual
Underwriters Laboratories Standard UL544
Canadian Standards Association Standard C22.2-125

4.0 General

This section provides a general description of the LifeBelt Resuscitation System (System). It is intended as an overview in preparation for the more detailed specifications and requirements documented in subsequent sections.

4.1 Overview

The System is an external electrically driven mechanical cardiocirculatory assistance system developed for use in the resuscitation of cardiac arrest victims in mobile and fixed locations. This resuscitation is accomplished by tightening and releasing a supple band which surrounds the chest of the victim. In addition, the placement of a concentrator between the sternum of the victim and the band focuses compression force on the sternum. The force applied by the band and the tighten/release repetition rate are programmed by the operator prior to the start of resuscitation and may be adjusted during resuscitation. In cases where power has failed or is unavailable, the System may be operated manually.

A concept drawing of one possible embodiment of the System is included as Figure 1.

4.2 Significant Features

- AC or battery operation
- Programmable force and repetition rate
- Emergency shut-off and quick release switch
- Manual operation via removable lever/crank
- Light weight with handle for carrying
- Data collection (for history and troubleshooting during service)
- Serial port for transfer of data to PC
- Self diagnostics
- Removable/replaceable belt
- Defibrillation mode

4.3 User of the Device

The System is intended to be used by healthcare professionals (hospital and EMT) and by private individuals trained in its use and the use of cardiopulmonary resuscitation.

4.4 Storage and Use Environments

The System is to be rugged enough to withstand normal use in an emergency vehicle. This includes vibration associated with transporting, impact associated with placement in and removal from an emergency vehicle, and temperature and humidity extremes associated with the weather.

4.5 Life Expectancy Goals

The goal for the average life of a System is 2 years.

5.0 Size, Weight, Etc. Requirements

5.1 Size
Length: 33" maximum
Width: 21" maximum
Height: 7" maximum

5.2 Weight: 25 lbs. maximum

5.3 Case Material: Plastic

5.4 The System must include an integral handle to facilitate easy manual handling and carrying.

6.0 Supple Band Requirements

The supple band for surrounding the victims chest and delivering resuscitative pressure must:

- be easily removed and replaced.
- be capable of withstanding 3 months of normal System operation
- be of a low friction material to resists chafing the victim
- be X ± Y" wide and long enough to accommodate a victim having a chest circumference of 60"

The supple band must be discontinuous at one point in order to facilitate its surrounding of the victim. The ends resulting from the discontinuity must contain a fastening means that is easily fastened and withstands the same range of tensions as the supple band itself.

An optional 15 ± z" extension section of the same material must be available to accommodate victims having chest circumferences in excess of 60".

7.0 Mechanism Requirements

Mechanism must be capable of consistently delivering, in a repetitive manner, a minimum of 0 (zero) lbs and a maximum of 1200 lbs of tension to the supple band. For purposes of this specification, the portion of each cycle that the band is at 1200 lbs of tension is assumed to 50%.

The range of repetition rates for tensing and relaxing the supple band is 60 to 100 cycles per minute.

The mechanism shall allow for manual tension and relaxation of the supple band via an attachable wrench. Obtaining a band tension of 1200 lbs must require no more than xx ft-lbs of torque by the wrench. It is considered acceptable to incorporate a motor disconnection means to meet this torque as long as such disconnection can be accomplished quickly, easily, and without the aid of tools other than the wrench. During manual operation of the System, an easily distinguishable indication of application of the desired pressure to the victim (± ____) must be provided.

8.0 Concentrator

A concentrator shall be provided for placement between the supple band and the victim's sternum. This concentrator shall be designed such that . . .

9.0 Electrical Requirements

9.1 Electrical Input

The System shall operate using either of the following:

- 115 VAC ± 10% @ x amps (max) via hospital grade integral AC power cord
- 12 VDC +1.5/-x @ y amps (max) via _____ connector

9.2 Serial Port

A standard RS-232 port shall be provided and shall be available for external connection via a 25 pin female D connector. This port is used for testing (see section x), reprogramming EEPROM (see section 9.4), and data transfer (see section y).

9.3 Nonvolatile Memory

x K bytes of nonvolatile memory shall be provided for storing data related to the actual use of the individual System. See section x for information on the actual data.

9.4 Program Memory

x K bytes of flash EEPROM shall be provided for System software. This EEPROM shall be programmable via the RS-232 serial port using _____ protocol. The EEPROM must be rated for a minimum of x programming cycles.

9.5 Mechanism Control

Means shall be provided for controlling the mechanism, thereby controlling the tension and

relaxation of the supple band. Such control is to include the following.

Removing slack in the supple band from both sides simultaneously until a tension of x ± y lbs. is present in the band
Applying tension to the supple band from both sides simultaneously until a operator preset ____ has been reached (± _____ ___). This pressure is to be applied at a rate equal to 4 X (preset maximum pressure - preset minimum pressure) X preset repetition rate (± _____).
Releasing tension on the supple band from both sides simultaneously until a predetermined ____ has been reached (± _____ ___). This pressure is to be released at a rate equal to 4 X (preset maximum pressure - predetermined minimum pressure) X preset repetition rate (± _____).

9.6 User Interface

9.6.1 Display

The System display is a ___ line by ____ character backlit Liquid Crystal Display. The height of the characters is ___ ± ___ inches.

9.6.2 Controls

The System must contain momentary contact switches marked with the following (or similar) legends and having the following functions:

Increase Rate - increase the preset tension/relaxation rate to be applied to the victim. Rate values range from 60 to 100 cycles per minute (cpm) in increments of 5 cpm.

Decrease Rate - decrease the preset tension/relaxation rate to be applied to the victim. Rate values range from 60 to 100 cycles per minute (cpm) in increments of 5 cpm.
Increase Pressure - increase the preset maximum pressure to be applied to the victim. Pressure values range from xx to yy ____ in increments of ____ ____.

Decrease Pressure - decrease the preset maximum pressure to be applied to the victim. Pressure values range from xx to yy ____ in increments of ____ ____.

Run/Stop - causes the System to begin resuscitating the victim.

9.6.3 Emergency Stop

A latching pushbutton switch with a large (minimum of ____ inches in diameter) red pushbutton must be provided with its pushbutton in an easily visible and accessible position in order to allow the System to be quickly halted in an emergency. This pushbutton switch must be directly in series with DC power such that it is impossible for the mechanism to operate with this switch in an "open" condition.

9.6.4 Power Switch

Power to the System (AC or DC) is to be turned on and off by a suitably rated rocker switch. This switch or a position on the System case adjacent to this switch must be clearly marked with the legends "1" (meaning on) and "0" (meaning off).

9.6.5 Display Sequences

Specifics concerning the information to be displayed under various situations (e.g. activation of a control) are shown in Figures 2 through __.

9.7 Time and Date Circuit

Provisions must be made for keeping track of the time of day and the date. Time passage must be accurately maintained within a tolerance of ____ seconds per month.

10.0 Software Requirements

Normal operation
Defibrillation mode
Calibration
Self diagnostics
Data collection and output
- records of use
  - victim S/N
  - pressure
  - rate
  - duration
  - date
  - time
  - System S/N
  - alarms
  - down time

- service data
  - alarm totals
  - quantity of resuscitations

Remote testing
Setting time and date

11.0 System Labeling

12.0 Safety Requirements

12.1 Third Party Certification
Underwriters Laboratories
Canadian Standards Association

12.2 Device Specific
Redundancy

13.0 Environmental Requirements

13.1 Electrostatic Discharge
Spec #

13.2 Electromagnetic Susceptibility
Spec #

13.3 Electromagnetic Interference
Spec #

13.4 Fluid Resistance
Spec #

13.5 Vibration
Spec #

13.6 Drop (Impact)
Spec #

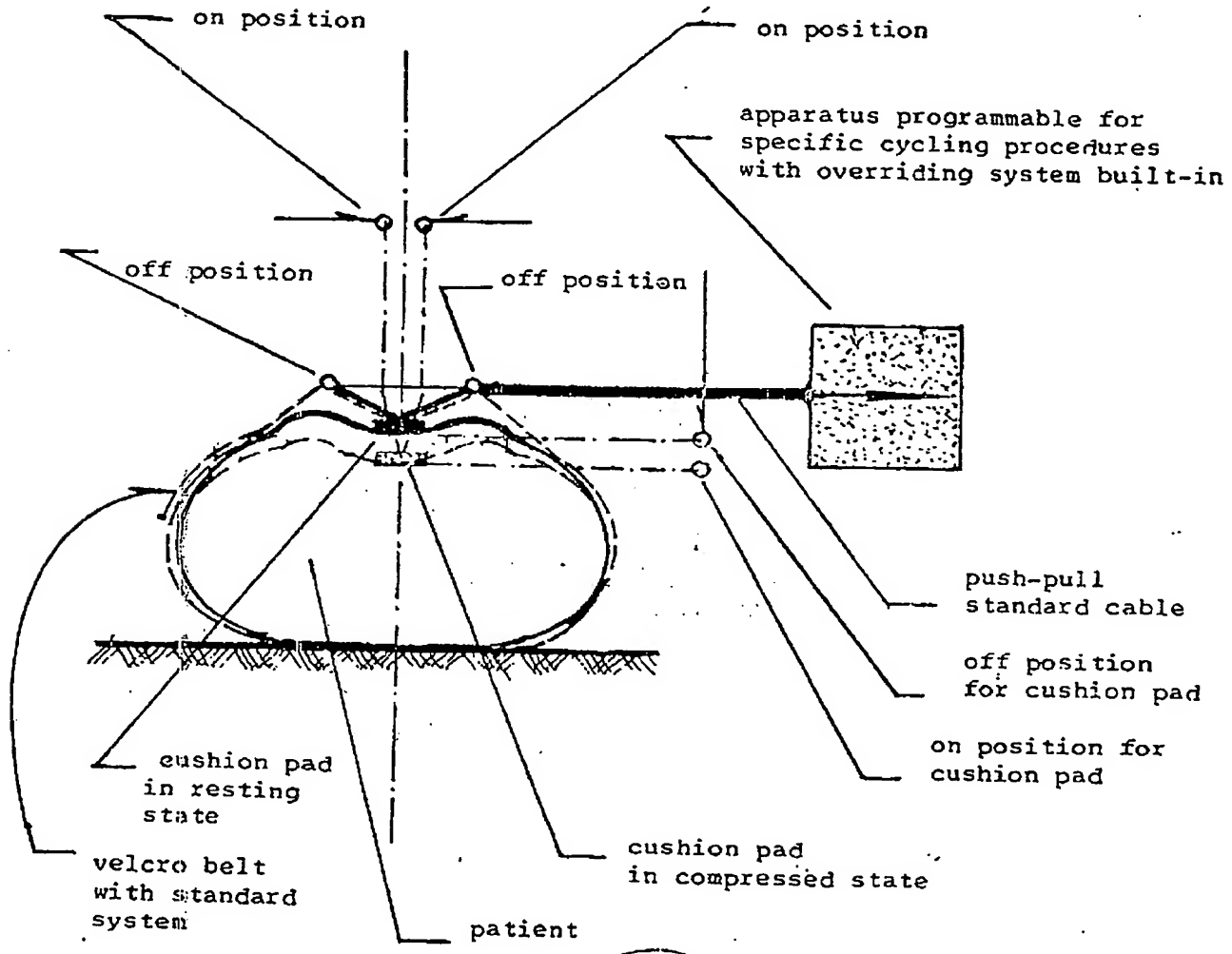
14.0 Regulatory Requirements

15.0 Packaging Requirements
Material
Vibration/Impact Requirements
Labeling

AUTOMATIC RESUSCITATOR

operated with electrical power DC or AC

and or compressed air, other gases, etc.



Inventor: Roman Szpur date: 7 Jan. 94

Roman Szpur

Read and Understood

Signature: [signature] date: 9-28-94

Signature: Kevin C. Kelly date: 9/28/94

Exhibit F

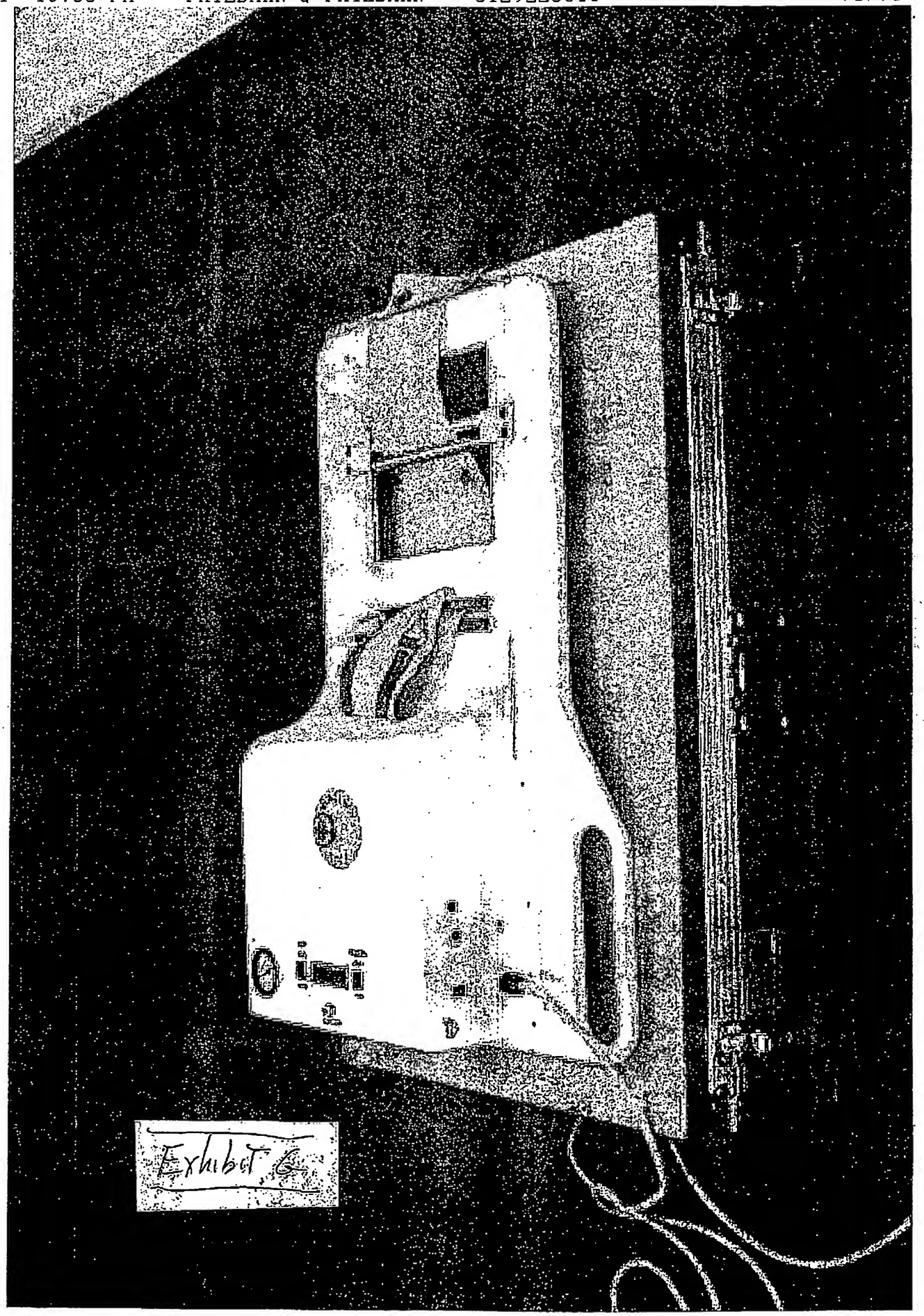


Exhibit G